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28075 7590 10/15/2009 CROMPTON, SEAGER & TUFTE, LLC 1221 NICOLLET AVENUE SUITE 800 MINNEAPOLIS, MN 55403-2420			EXAMINER YABUT, DIANE D	
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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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*Ex parte* DENNIS O'BRIEN and CARL YEE

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Appeal 2009-005178  
Application 10/725,178  
Technology Center 3700

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Decided: October 15, 2009

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Before LINDA E. HORNER, STEFAN STAICOVICI, and  
KEN B. BARRETT, *Administrative Patent Judges*.

STAICOVICI, *Administrative Patent Judge*.

DECISION ON APPEAL

## STATEMENT OF THE CASE

Dennis O'Brien et al. (Appellants) appeal under 35 U.S.C. § 134 from the Examiner's decision rejecting claims 1-5 and 8-14<sup>1</sup>. We have jurisdiction over this appeal under 35 U.S.C. § 6 (2002).

## THE INVENTION

Appellants' invention relates to a catheter 20 having a cutting balloon 22 including an inflatable balloon 30, a plurality of incising elements 44 encapsulated in respective mounting pads 46, and a compressible sheath 50 for each incising element 44. Spec. 5, ll. 2-3, 25-26, and 30-31; Spec. 6, ll. 7-9; and figs. 1-3. During transit to the treatment site, sheath members 52a, 52b of sheath 50 protect cutting edge 48 of incising element 44. When reaching the treatment site, the inflatable balloon 30 expands so that sheath members 52a, 52b contact tissue 58. Further expansion of the balloon 30 results in radial compression of sheath components 52a, 52b so that cutting edge 48 is exposed for tissue incision. Spec. 7, ll. 3-13 and fig. 4.

Claim 1 is representative of the claimed invention and reads as follows:

1. A cutting balloon for use on a medical catheter to incise tissue at a treatment site in a body vessel of a patient, said cutting balloon comprising:

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<sup>1</sup> Claims 15-24 are indicated as allowable by the Examiner. Claims 6 and 7 are objected to by the Examiner as being dependent upon a rejected base claim and otherwise indicated as being allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claim. Final Rejection 7, mailed Oct. 2, 2007. Claims 6, 7, and 15-24 are not part of the instant appeal.

an elongated balloon defining a longitudinal axis, said balloon being inflatable from a first deflated configuration to a second radially expanded configuration;

an elongated incising element mounted on said balloon and oriented longitudinally, said incising element having a length and extending radially from said balloon to an operative surface feature capable of incising tissue; and

a radially compressible sheath mounted on said balloon along the length of said incising element and extending radially from said balloon and beyond said surface feature when said balloon is in the first configuration to protect said surface feature during transit to the treatment site, said sheath being positioned for radial compression between said tissue and said balloon to expose said surface feature for tissue incision when said balloon is inflated into the second configuration.

### THE REJECTIONS

The Examiner relies upon the following as evidence of unpatentability:

Vigil	US 5,320,634	Jun. 14, 1994
Barath	US 5,616,149	Apr. 1, 1997

The following rejections are before us for review:<sup>2</sup>

The Examiner rejected claims 1, 2, 5, 8, and 10 under 35 U.S.C. § 102(b) as anticipated Barath.

The Examiner rejected claims 11-14 under 35 U.S.C. § 103(a) as unpatentable over Barath.

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<sup>2</sup> We note that the Examiner has presented new grounds of rejection and Appellants have properly responded thereto. Ans. 3 and Reply Br. 1.

The Examiner rejected claims 3, 4, and 9 under 35 U.S.C. § 103(a) as unpatentable over Barath and Vigil.

### THE ISSUE

Appellants argue that Barath fails to teach a sheath that is “*radially compressed to expose the surface feature* for tissue incision,” as required by independent claim 1. App. Br. 10. Further, Appellants note that in contrast to the claimed invention, “the cutting edges 6 [of Barath] are *exposed by the inflation of the balloon 2*” and not by radial compression of the sheath 17 against the vessel wall. App. Br. 10 and 12.

In response, the Examiner takes the position that:

In Figures 12-13 of Barath, the sheath 17 is shown being positioned for radial compression between the tissue 7 and the balloon 2 while also exposing the surface feature 6. Radial compression of the sheath 17 may be achieved during inflation of the balloon, wherein the sheath may be pressed and held between the tissue and the balloon, while also exposing the surface features 6, and therefore the device of Barath reads on this limitation.

Ans. 7.

The Examiner appears to take the position that because the sheath 17 of Barath is positioned between the wall 8 and the inflatable balloon 2, the sheath 17 constitutes a “radially compressible sheath.” The Examiner further posits that claim 1 does not require that the exposure of the surface feature for tissue incision be caused by the radial compression of the sheath. According to the Examiner, claim 1 merely requires that the sheath 17 of Barath be positioned for radial compression, that is, be positioned so as to be

compressed between the balloon and the tissue while also exposing the surface feature for tissue incision.

Accordingly, the issue before us for consideration in the instant appeal is whether Appellants have shown that the Examiner erred in determining that the sheath 17 of Barath constitutes a “radially compressible sheath,” as called for by claim 1.

## SUMMARY OF DECISION

We REVERSE.

## PRINCIPLES OF LAW

### Claim Construction

When construing claim terminology in the United States Patent and Trademark Office, claims are to be given their broadest reasonable interpretation consistent with the specification, reading claim language in light of the specification as it would be interpreted by one of ordinary skill in the art. *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364 (Fed. Cir. 2004).

### Anticipation

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros, Inc.. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631 (Fed. Cir. 1987).

### Inherency

Under principles of inherency, when a reference is silent about an asserted inherent characteristic, it must be clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that

it would be so recognized by persons of ordinary skill. *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991).

## OPINION

We begin our analysis by construing the limitation of “a radially compressible sheath... being positioned for radial compression between said tissue and said balloon to expose said surface feature for tissue incision when said balloon is inflated.” As noted above, claims are to be given their broadest reasonable interpretation consistent with the specification. In this case, claim 1 requires: (1) a radially compressible sheath (2) positioned for radial compression between said tissue and said balloon and (3) a surface feature for tissue incision exposed when the balloon is inflated.

It is our finding that Barath teaches a cutting balloon catheter including a protective sheath 17 that is positioned between an inflatable balloon 2 and a vessel wall 7, 8 (tissue), so that as the balloon 2 is inflated cutting edges 6 (surface feature for tissue incision) are exposed to penetrate the vessel wall 8 (tissue). Barath, col. 5, ll. 30-34 and fig. 13. Hence, in a first instance, Barath teaches a sheath 17 that is positioned for radial compression between the tissue and the balloon, and a surface feature for tissue incision (cutting edges 6) that is exposed when the balloon is inflated. However, as shown above, claim 1 also requires a “radially compressible sheath.” Although we agree with the Examiner that claim 1 does not require actual radial compression of the sheath (Ans. 7), nonetheless, in order to satisfy the limitation of claim 1, we find that the sheath 17 of Barath should be capable of radial compression. However, Barath teaches only that the protective sheath 17 is positioned between the inflatable balloon 2 and the

vessel wall 8 (tissue). We could not find any portion, and the Examiner has not pointed to any portion of Barath, that teaches sheath 17 to be capable of radial compression. Moreover, the Examiner states that:

Radial compression of the sheath 17 *may* be achieved during inflation of the balloon, wherein the sheath *may* be pressed and held between the tissue and the balloon...

Ans. 7 (emphasis added).

Since Barath does not expressly teach that sheath 17 is capable of radial compression, the Examiner appears to rely on a theory of inherency to show that Barath anticipates the subject matter of claim 1. “Inherent anticipation requires that the missing descriptive material is ‘necessarily present,’ not merely probably or possibly present, in the prior art.” *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1295 (Fed. Cir. 2002) (quoting *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999)). In this case, the question raised is whether the sheath 17 of Barath is *necessarily* capable of radial compression. Figure 13 of Barath specifically shows cutting edges 6 penetrating the vessel wall 8 prior to the radial compression of sheath 17 between balloon 2 and wall 8 (see the space between the sheath 17 and wall 8).<sup>3</sup> In other words, the length of the cutting edges 6 (surface feature for tissue incision) is such that penetration of the vessel wall due to expansion of the inflatable balloon occurs before the sheath 17 is radially compressed between the balloon and the vessel wall. As such, we agree with Appellants

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<sup>3</sup> In Figure 13 of Barath the reference number “15” appears in error. The reference number 15 represents a casing shown in a different embodiment presented in Figures 9 and 10. *See also* Barath, col. 5, ll. 1-13. We find that the reference number “15” in Figure 13 represents the sheath 17.

that the sheath 17 of Barath is not *necessarily* capable of radial compression, as the Examiner suggests. *See* Reply Br. 5. In conclusion, we find that the Examiner has not provided sufficient evidence to support the finding that sheath 17 of Barath constitutes a “radially compressible sheath,” as called for by claim 1.

Inasmuch as we found that Barath does not teach a cutting balloon having a “radially compressible sheath,” as called for by independent claim 1, Barath does not teach all the elements of independent claim 1. Accordingly, the rejection of claims 1, 2, 5, 8, and 10 under 35 U.S.C. § 102(b) as anticipated by Barath cannot be sustained.

With respect to claims 11-14, the Examiner’s proposed modification of the disclosure of Barath (Ans. 5) does not cure the deficiencies of Barath as discussed above. Accordingly, the rejection of claims 11-14 under 35 U.S.C. § 103(a) as unpatentable over Barath likewise cannot be sustained.

Finally, regarding claims 3, 4, and 9, we find that the application of Vigil does not cure the deficiency of Barath as discussed above. Accordingly, the rejection of claims 3, 4, and 9 under 35 U.S.C. § 103(a) as unpatentable over Barath and Vigil is also reversed.

### CONCLUSION

Appellants have shown that the Examiner erred in determining that the sheath 17 of Barath constitutes a “radially compressible sheath,” as called for by claim 1.

Appeal 2009-005178  
Application 10/725,178

DECISION

The Examiner's decision to reject claims 1-5 and 8-14 is reversed.

REVERSED

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CROMPTON, SEAGER & TUFTE, LLC  
1221 NICOLLET AVENUE  
SUITE 800  
MINNEAPOLIS, MN 55403-2420